DELAWARE HEALTH AND SOCIAL SERVICES
HSRB PROJECT REPORT
Revised March 2002

INTERIM REPORT ☐ FINAL REPORT ☐

Original Approval Date: _____

Date of Previous Review: _____

1. Title of Project:

2. Principal Investigator (name, mailing address, phone #, e-mail address):

3. Co-Investigators (name, mailing address, phone #, e-mail address):

4. Has the study been initiated? Yes _____ No_____

5. Please provide a brief (no more than 2 sentences, if possible) description of this project.

6. How many potential subjects were approached to enter into the project? __________

(must equal GRAND TOTAL below)

a. Subject status:

1. Active ……………..................... ....__________(a1)
2. Completed ....……….. .... _____ ___(a2)
3. Lost to follow-up ....__________(a3)

(Attach explanations)

Total (sum of a1, a2, a3) ....
……….. __________ **(a)**

b. Subjects **dropped** from study, categorized by reason:

1. Voluntarily ....__________(b1)

(Attach explanations)

2. By investigator........ ....__________(b2)

(Attach explanations for dropping each subject)

3. Due to Adverse Events.................... ....__________(b3)

*(Attach explanation for **each subject dropped** due to an adverse event and include a description of efforts made to ameliorate the adverse impact)*

4. Due to project-related death during active phase of study ....__________(b4)

(Attach explanations of deaths.)

5. Due to non-project-related death during active phase of study ....__________(b5)

Total Subjects Dropped (sum of b1, b2, b3, b4, & b5)…__________

(**b**)

c. Potential subjects who **declined** to participate: ....
…_________**(c)**

(Attach summary/tabulation/analysis of reasons subjects gave for declining)

d**. *GRAND TOTAL (*sum of a, b & c)........ ....__________ (d)**

7. What is the status of this project?

a. Open __________

b. Closed to subject accrual Date_____

c. Closed Date_____

If closed: reason_____

d. On hold Date _____

If on hold: reason _____

e. Cancelled Date_____

If cancelled: reason_____

8. Please describe ***any*** adverse events or unanticipated problems involving risks to subjects who have remained in this study, including the number of subjects involved (attach relevant reports or documents). Include a description of intervention(s) used for subjects adversely affected. [Note: This information is a summary of what has already been provided to the Board IMMEDIATELY upon the occurrence of an adverse event. Also, this is in addition to the information provided in item 6b, which involves subjects who **dropped out** of the study.]

9. For projects utilizing questionnaires, please delineate any specific question(s) that **one** or more subjects refused to answer. The actual question(s) should be listed – with the number of persons who refused to answer. If respondent(s) displayed significant stress when a 'refused' question was posed, identify that question and describe how the stress was ameliorated. For those questions where the refusal rate was significant, please discuss the ramifications (for instance, should changes of any kind be made to the study's design – if the study is still in progress? If the project is over, are there changes that, in retrospect, you would have made – now that this information is known?). If none of the questions had a significant number of "refusals," please so indicate.

10. Did any of the subjects experience decreased capacity after the study began, such that they were no longer able to give informed consent or voluntarily withdraw from participation? If so, how was that issue addressed in each instance? Were surrogate decision makers consulted? Did such individuals in fact continue in the study?

11. Has additional or new information become available on this study **or related studies** which subjects need to know, particularly information that might affect their willingness to continue to participate?

Yes _____ No _____

If Yes, please explain (include any recent literature, findings or other relevant information, especially about risks associated with the research) and describe the process that has been used

to convey this information to those whose participation is over and those still active in the research :

***For INTERIM REPORTs, attach a Narrative describing the Project's status and detailing any preliminary Project findings. Also attach a copy of the current* consent form.**

For FINAL REPORTs, attach Executive Summary with Project findings.

_____ _____

INVESTIGATOR'S SIGNATURE **REPORT DATE**